June 21, 2019

Zimmer MedizinSysteme GmbH
℅ Scott Blood
Principal Regulatory Consultant
Quality and Regulatory Services
22 Nichols Street #2
Salem, Massachusetts 01970

Re: K182963
Trade/Device Name: emFieldPro
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: May 15, 2019
Received: May 16, 2019

Dear Scott Blood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Vivek Pinto, PhD
Assistant Director, Acute Injury Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182963

Device Name
emFieldPro

Indications for Use *(Describe)*
emFieldPro is indicated to be used for:
• Improvement of abdominal tone, strengthening of the abdominal muscles, development for firmer abdomen.
• Strengthening, toning and firming of buttocks and thighs.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K182963

1. Basic Information-Submitter:

510(k) Owner:	Zimmer MedizinSysteme GmbH Junkersstrasse 9 89231 Neu-Ulm Germany Establishment Registration: 8010720
Official Contact:	Mrs. Ute Hauss Manager Regulatory Affairs Phone: +49-731-9761-216 Fax: +49-731-9761-118 E-mail: u.hauss@zimmer.de

Date Summary Prepared:	14 May 2019

2. Device Name:

Trade Name:	emFieldPro
Common Name:	Powered muscle stimulator
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation Number:	21 CFR 890.5850
Product Code:	NGX
Classification:	Class II

3. Predicate Devices: BTL 799-2 – K180813

4. Device Description:

emFieldPro is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body. By muscle stimulation, the emFieldPro helps to strengthen, tone and firm the abdomen, buttocks and thighs.

The device housing protects the patient from electrical shock and mechanical injuries. The device is mobile standalone equipment with four wheels. Two applicators are available for therapy: a large and a small one. The main body of emFieldPro is used to control function of magnetic stimulation. It is operated with parameters such as Frequency, Time and Intensity. These parameters can be controlled by the user on LCD and with the help of a rotary knob at the user control panel.

5. Indications for Use Statement:

emFieldPro is indicated to be used for:

- Improvement of abdominal tone, strengthening of the abdominal muscles, development for firmer abdomen.
- Strengthening, toning and firming of buttocks and thighs.

6. Technological Characteristics:

The emFieldPro device has the same indications for use and similar technological characteristics and principles of operation as its predicate device. The emFieldPro device and its predicate are comprised of a system console and applicator. The system console consists of the electromagnetic field generators, computer, and the touch-screen control panel.

The emFieldPro is equipment that generates a magnetic field by applying a strong current to an applicator. The essential technical characteristics of the emFieldPro and its predicate device, particularly the type of energy, type of operation, therapy time and the Magnetic Field Intensity are equivalent.

Compared to the predicate, the emFieldPro device is equipped with an arm which allows adjustment of the applicator right in front of the patient in an optimized position for treatment.

The technological differences between the emFieldPro device and the predicate device do not raise any new types of safety or effectiveness questions.

Technological Characteristics	**SUBJECT DEVICE** **Zimmer MedizinSyteme GmbH** **emFieldPro** **K182963**	**PREDICATE DEVICE** **BTL Industries, Inc.** **BTL 799-2** **K180813**
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 NGX – Stimulator Muscle, Powered, Muscle Conditioning	Physical Medicine 21 CFR 890.5850 NGX – Stimulator Muscle, Powered, Muscle Conditioning
Indications for Use	The emFieldPro is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.	BTL 799-2 is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.
Primary Function	Muscle stimulation	Muscle stimulation
Principle of Action	Initiating action potential of nerves	Initiating action potential of nerves

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSyteme GmbH emFieldPro K182963	PREDICATE DEVICE BTL Industries, Inc. BTL 799-2 K180813
	results in muscle contraction	results in muscle contraction
Electrical Protection	Class I, BF	Class II, BF
User Interface	Touch screen	Touch screen
Touch screen size	7”	15.6" (39.6 cm)
Firmware Controlled	Yes	Yes
Type of Energy	Magnetic field	Magnetic field
Number of outputs	2	2
Number of Magnetic Coils in the Applicator	1	1
Magnetic Field Intensity	Large applicator 0.5 – 1.5T +/-20% Small applicator 0.5 – 2T	0.5–1.8 T
Total Induced Current in Tissue (mA)	251	285
Type of Operation	Continuous	Continuous
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz
Pulse Duration	400 µs +/- 20%	280 +/- 20% µs
Pulse Amplitude	0 – 100 %	0 – 100 %
Selection of parameters (Intensity, Time)	Yes	Yes
Therapy Time	Up to 60 min	Up to 60 min
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave
Energy Source	100 – 240 VAC, 50/60 Hz	100 – 240 V AC, 50–60 Hz
System Dimensions (WxHxD)	542x501x993mm	500×1380×580 mm (20×55×23 in)
Operating Ambient Temperature	10°C to 30 °C	-10°C to +55°C
Environmental Specifications	For indoor use only	For indoor use only

The Zimmer MedizinSysteme GmbH emFieldPro has the same technological characteristics as the predicate device except for the following:

Technological Characteristic	Characteristic difference between emFieldPro and Predicate Device	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
Electrical Protection	Class I versus Class II	Electrical safety is covered as class 1 device equal to a class 2 device.
Touch Screen Size	7’’ versus 15.6" (39.6 cm)	Even the size of the touch screen of emFieldPro is smaller than the predicate device all icons and data are displayed clearly and usability is passed successfully.

Technological Characteristic	Characteristic difference between emFieldPro and Predicate Device	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
Magnetic Field Intnesity	0.5 – 1.5T +/- 20% for the large applicator ad 0.5 – 2.0T for the small applicator versus 0.5 to 1.8T	The maximum field intensity for the emfieldPro's small applicator is 2.0T as compared to the 1.8T of the predicate device. This difference is within 20% of the acceptable variability in field intensity.
Total Induced Current in Tissue (mA)	251 mA versus 285 mA	The total induced current on the tissue for the emFieldPro is less than the predicate device and therefore safer with the same effect. The difference between the two induced current measurements are within just over 10%, which is not great enough of a variation to produce a different clinical effect.
Pulse Duration	400 µs +/- 20% for the large applicator and 250µs +/- 20% for the small applicator versus 280 +/- 20% µs at the predicate device	The pulse width of the emFieldPro device and the predicate device are in the typical clinical range of 50 to 500µs Reference: "the effect of stimulus current pulse width on nerve fiber size recruitment patterns" by Robert B. Szlavik and Hubert de Bruin
System Dimensions (WxHxD)	501x993x542 mm versus 580×1380×580 mm	Different dimensions have no influence on the safety or effectiveness of the device. The usability is passed successfully.
Operating Ambient Temperature Range	10°C to 30 °C versus -10°C to +55°C	The emFieldPro labeling allows for device usage in an environment that is more typical than the environment stated in the predicate labeling

Any differences in their technological characteristics are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness.

7. Performance data

The emFieldPro device has been investigated and tested against and complies with the following voluntary standards:

Standards	Standards Organization	Standards Title
60601-1	IEC	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-2	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
60601-1-6	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
60601-2-10	IEC	Medical electrical equipment – Part 2-10: Particular requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators

Standards	Standards Organization	Standards Title
62366-1	IEC	Medical devices – Application of usability engineering to medical devices
62304	IEC	Medical devices software –software life cycle processes
14971	ISO	Medical devices – Application of risk management to medical devices
10993-1	ISO	No Biocompatibility testing performed as the applied doesn't get in contact with the patient (see section 16)

The following table shows a comparison of the performance testing in comparison to the predicate devices:

Standards	SUBJECT DEVICE Zimmer MedizinSyteme GmbH emFieldPro K182963	PREDICATE DEVICE BTL Industries, Inc. BTL 799-2 K180813
IEC 60601-1	X	X
IEC60601-2-10	X	X
IEC 60601-1-2	X	X
ISO 10993-1	Not applicable (no patient-contacting materials)	X

According to this comparison table all required performance tests were conducted and show substantial equivalence with the predicate devices.

Preclinical Testing Results

The following tests were performed on the subject device in addition to the testing listed above:

- Magnetic Field testing
- Tissue Heating study

The testing above confirmed that the large and small applicator each operate within the magnetic field intensity specifications for each applicator and that the tissue being treated by the device does not present an appreciable rise in temperature at maximum intensity to cause a risk to the patient.

Testing has been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

8. 510(k) Summary:

Zimmer MedizinSysteme GmbH has demonstrated that the emFieldPro device is substantially equivalent to the predicate device listed above.